K023155

NOV 25 2002

Attachment 7
510(k) Summary

September 20, 2002

1. Submission Applicant & Correspondent:
Name: Sinclair Pharmaceuticals, Ltd.
Address:
Borough Road
Godalming
Surrey
GU7 2AB
United Kingdom

Phone No.: +44 (0) 1483 428 611
Contact Person: Denise Swift, Director of Regulatory Affairs

2. Name of Device:	**ALOCLAIR™ ORAL RINSE**
Trade/Proprietary/Model Name:	**ALOCLAIR™ ORAL RINSE**
Common or Usual Name:	Dressing, Wound & Burn, Hydrogel w/Drug or Biologic
Classification Names:	Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

3. Devices to Which New Device is Substantially Equivalent:

Sinclair Gelclair Concentrated Oral Gel cleared in 510(k) K013056

AloeCeuticals (Carrington Lab) OraRinse cleared in 510(k) K983182

4. Device Description:
ALOCLAIR™ ORAL RINSE is a viscous gel formulation, which is presented for over-the-counter use premixed in containers of various sizes with plastic measuring cup. This combination of substances, when washed around the mouth, forms a protective layer over the oral mucosa.

5. Intended Use of the Device:

SINCLAIR ALOCLAIR™ ORAL RINSE Aloclair Oral Rinse with Aloe Vera extract, adheres to the mucosal surface and provides rapid pain relief from aphthous ulcers, canker sores, and minor oral lesions, including ulcers caused by braces and ill fitting dentures.

6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:

The **ALOCLAIR™ ORAL RINSE** has the same intended/indications for use as the predicate Sinclair Gelclair™ Concentrated Oral Gel and AloeCeuticals (Carrington Lab) OraRinse™ .

Product Name	*Aloclair*	*Gelclair*	*OraRinse*
Method of Use	Pre-mixed	Mix with water	Mix with water
# of applications per day	Take as needed	Take as needed	Take as needed
Claim	Management and relief of pain, non irritating, does not sting, safe if swallowed	Management and relief of pain, non irritating, does not sting, safe if swallowed	Rapid relief from pain, pleasant taste, does not sting, safe if swallowed
Area of Use	Oral Mucosa	Oral Mucosa	Oral Mucosa
Disease State	Aphthous Ulcers, Canker Sores, Oral lesions	Oral Mucositis/Stomatitis, Oral lesions	Apthous Ulcers and Canker Sores, Oral lesions
Type of Product	Oral Rinse/Mouthwash	Oral Rinse Concentrate for dilution	Oral Rinse Concentrate for dilution
Presentation	Non Sterile	Non Sterile	Non Sterile

7. Tests and Conclusions:
Functional and performance testing were conducted to assess the safety and effectiveness of Aloclair® ORAL RINSE. All results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 2002

Ms. Denise Swift
Director, Regulatory Affairs
Sinclair Pharmaceuticals Limited
Borough Road,
Godalming, Surrey, GU 7 2AB
UNITED KINGDOM

Re: K023155
Trade/Device Name: Sinclair Aloclair™ Oral Rinse
Regulation Number: 21 CFR 878.4022
Regulation Name: Hydrogel Wound Dressing and Burn Dressing
Regulatory Class: Unclassified
Product Code: MGQ
Dated: September 20, 2002
Received: September 23, 2002

Dear Ms. Swift:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613 . Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3

Indications for Use Statement

510(k) Number (if known) K023155

Device Name SINCLAIR ALOCLAIR™ ORAL RINSE

Indications for Use

SINCLAIR ALOCLAIR™ ORAL with Aloe Vera extract, adheres to the mucosal surface and provides rapid pain relief from aphthous ulcers, canker sores, and minor oral lesions, including ulcers caused by braces and ill fitting dentures.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K023155

Prescription Use _____ OR Over-The Counter Use ✓
(per 21 CFR 801.109)